

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY
GMBH, BAYER ANIMAL HEALTH
GMBH, and BAYER HEALTHCARE, LLC,

Plaintiffs,

v.

CAP IM SUPPLY, INC.,

Defendant.

Civil Action No. 17-cv-591-RGA

MEMORANDUM OPINION

Jack Blumenfeld, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE; Gary H. Levin (argued), Stephanie M. Papastephanou, Timothy J. Doyle, and Samuel A. McMahon, BAKER HOSTETLER LLP, Philadelphia, PA; Irene E. Hudson, BAKER HOSTETLER LLP, New York, NY.

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ANDREWS, U.S. DISTRICT COURT JUDGE:

Presently before the Court are Plaintiffs' motion for preliminary injunction (D.I. 6), and Defendant's cross-motion for summary judgment of non-infringement (D.I. 58), and Defendant's motion to strike (D.I. 96) both the declaration of Dr. Alan White (D.I. 81) and Plaintiffs' reply brief in support of their motion for preliminary injunction (D.I. 78). The issues have been fully briefed. (D.I. 7, 59, 78). The Court held oral argument on February 23, 2018. (D.I. 115). For the reasons stated herein, Plaintiffs' motion for preliminary injunction and Defendant's cross-motion for summary judgment are **DENIED**.

I. BACKGROUND

Plaintiffs assert U.S. Patent No. 7,728,011 ("the '011 patent"), which issued on June 1, 2010, and covers spot-on solutions for controlling fleas, ticks, and mosquitoes on animals. (D.I. 7, p. 1). Claim 1 of the '011 patent reads as follows:

1. A composition for controlling parasites on an animal comprising:
 - a. from about 35% to about 60% by weight of permethrin;
 - b. from about 2.5% to about 12.5% by weight of imidacloprid or an analog;
 - c. from about 27.5% to about 62.5% by weight of N-methylpyrrolidone;
 - d. from 0% to about 5% by weight of water;
 - e. from 0% to about 0.5% by weight of phenolic antioxidants; and
 - f. from 0% to about 0.5% by weight of at least one organic acid.

('011 patent, claim 1). Plaintiffs' K9 Advantix®II product embodies the '011 patent. (D.I. 7, p. 1). Its active ingredients are imidacloprid, permethrin, and pyriproxyfen, all of which are dissolved in the solvent N-methylpyrrolidone ("NMP"). (*Id.*). Plaintiffs distribute K9 Advantix®II in veterinary clinics and the pet specialty channel, which includes large pet-specialty retailers. (*Id.*).

In 2014, Defendant began developing the accused products, which contain the same active ingredients as K9 Advantix®II. (D.I. 59, p. 2). The accused products' active ingredients are dissolved in a mixture of NMP and another solvent, dimethyl sulfoxide ("DMSO"). (*Id.*).

Specifically, Defendant's Advecta^{TM3} product contains 45.02% by weight permethrin; 8.80% by weight imidacloprid; 36.35% of an NMP/DMSO mixture, namely: 18.88% by weight NMP and 17.47% by weight DMSO; 0.39% by weight water, 0.11% by weight BHT (a phenolic antioxidant); and 0.03% by weight citric acid (an organic acid). (D.I. 7, p. 12).

In April 2015, Defendant provided Plaintiffs with descriptions of the formulations of two of the accused products. (D.I. 60 at 13-14). Plaintiffs' August 19, 2015, response indicated that Plaintiffs could not assess infringement at that time, and could not do so until Defendant's formulations received marketing approval. (*Id.* at 14). In October 2015, Defendant sent a response letter taking the position that market approval is not necessary to assess infringement. (*Id.*). Though Defendant sent follow-up letters in December 2015 and June 2016, Defendant received no substantive response from Plaintiffs until September 15, 2016, when Plaintiffs sent Defendant a notice letter asserting that Defendant's products may infringe the '011 patent. (*Id.*; D.I. 63-4 at 50). Defendant replied by letter on September 28, 2016, denying infringement and offering to discuss the matter further. (*Id.* at 51-52). On October 28, 2016, Plaintiffs replied, seeking compensation for Defendant's use of Plaintiffs' data to obtain EPA registration for its products, but making no mention of infringement. (*Id.* at 53-54). Defendant launched the accused products in January 2017. (D.I. 59, p. 3). Plaintiffs purchased two boxes of Defendant's Advecta^{TM3} product on January 30, 2017, for testing by a third party. (D.I. 9, ¶¶ 3-5). The preliminary results were provided to Plaintiffs on March 7, 2017 (D.I. 10, ¶ 20), and the final results were completed on April 20, 2017 (D.I. 78, p. 19). Plaintiffs filed their complaint on May 22, 2017 (D.I. 1), and filed this motion approximately two weeks later on June 5, 2017 (D.I. 6).

The spot-on product market comprises multiple generic and branded competitors and products, such as Bayer's K9 Advantix^{®II} product, Frontline's fipronil product, and Sergeant's

fipronil generics. (D.I. 115 at 21:15-22:23; D.I. 63-9 at 63-64, 78). As of June 2017, the entire spot-on product market was declining, due in part to customer migration to flea and tick products with other modes of administration, such as orally-administered products. (D.I. 115 at 20:23-21:1, 51:2-5; D.I. 63-9 at 76).

II. LEGAL STANDARD

A. Summary Judgment

“The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). Material facts are those “that could affect the outcome” of the proceeding, and “a dispute about a material fact is ‘genuine’ if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party.” *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)).

B. Preliminary Injunction

Pursuant to 35 U.S.C. § 283, a court in a patent case “may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.” 35 U.S.C. § 283.¹ “The grant or denial of a preliminary injunction under 35 U.S.C. § 283 is within the sound discretion of the district court.” *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1334 (Fed. Cir. 2006). The Federal Circuit has “cautioned, however,

¹ “[A]lthough a procedural matter,” because motions under 35 U.S.C. § 283 “involve[] substantive matters unique to patent law,” they are governed by the law of the Federal Circuit. See *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 n.12 (Fed. Cir. 1988).

that a preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted.” *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993).

To obtain a preliminary injunction, a movant must establish: “(1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction’s favorable impact on the public interest.” *Amazon.com, Inc., v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). “These factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested.” *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988). The Federal Circuit, however, has placed particular emphasis on the first two factors: “a movant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors, *i.e.*, likelihood of success on the merits and irreparable harm.” *Amazon.com*, 239 F.3d at 1350 (emphasis in original). Accordingly, “[w]hile granting a preliminary injunction requires analysis of all four factors, a trial court may . . . deny a motion based on a patentee’s failure to show any one of the four factors—especially either of the first two—without analyzing the others.” *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1356 (Fed. Cir. 2002); *see also Amazon.com*, 239 F.3d at 1350; *Chrysler Motors Corp. v. Auto Body Panels of Ohio, Inc.*, 908 F.2d 951, 953 (Fed. Cir. 1990) (“If the injunction is denied, the absence of an adequate showing with regard to any one factor may be sufficient, given the weight or lack of it assigned the other factors, to justify the denial.”).

III. DISCUSSION

A. Summary Judgment

Defendant argues that it is entitled to summary judgment because Plaintiffs do not assert literal infringement, and they are precluded from asserting infringement under the doctrine of

equivalents as a matter of law. (D.I. 59, pp. 1-8). Plaintiffs acknowledge that the accused product does not literally infringe but argue that they are likely to succeed in establishing infringement on the merits under a doctrine of equivalents theory. (D.I. 7, pp. 11-12). Defendant responds that Plaintiffs may not rely on a doctrine of equivalents theory because (1) they claimed only NMP as a solvent, (2) claim differentiation precludes the claims from covering equivalent solvents to NMP, and (3) Plaintiffs forfeited any doctrine of equivalents argument when they relied on unexpected results to overcome a prior art rejection during prosecution. (D.I. 59, pp. 4-8).

Defendant first asserts that Plaintiffs have forfeited the ability to argue the doctrine of equivalents to cover equivalent solvents because Plaintiffs claimed only NMP as a solvent. (D.I. 59, p. 4 (relying on *Tanabe Seiyaku Co. v. U.S. Int'l Trade Comm'n*, 109 F.3d 726, 733 (Fed. Cir. 1997) for the proposition that, “When well-known compounds exist that are often used for a similar purpose . . . yet the patentee only claims one such compound, the omission indicates a surrender of the other well-known compounds”)). Defendant alleges that “DMSO as a solvent in parasiticides was well-known at the relevant time,” as demonstrated by Plaintiffs’ other patents that included DMSO as a solvent and were filed before the priority date for the ’011 patent. (*Id.* p. 5). Given that DMSO, like NMP, was known to be a polar organic solvent, Defendant submits that a person of ordinary skill “could have used any number of claiming tools to encompass a broader range of solvents than just NMP.” (*Id.*). Defendant maintains that the patentees “knew how to claim broader categories of the claimed elements when [they] so intended,” evidenced by the fact that “[a]ll of the listed excipients in the claims of the ’011 patent (other than water) refer to broad categories of compounds.” (*Id.* p. 4). The patentees’ choice to claim NMP specifically thus further supports finding a forfeiture. (*Id.*). Therefore, Defendant contends, the patentees forfeited the ability to use the doctrine of equivalents to cover a solvent other than NMP. (*Id.*).

Plaintiffs respond that *Tanabe* is not as broad as Defendant states. They distinguish *Tanabe* on the basis that there, “the asserted equivalent was within a class of compounds that was either explicitly or implicitly distinguished from the claim element.” (D.I. 78, p. 2). Plaintiffs assert *Tanabe*’s holding stemmed from the patentee’s knowledge and indications in the prosecution history that other members of the claimed solvent class may not work and “may result in lower yields than the claimed solvents.” (*Id.* pp. 2-3). Here, by contrast, Plaintiffs point out that DMSO does not fall within the same solvent class as any of the solvents that the patentees distinguished during prosecution. (*Id.* p. 3; *see* D.I. 61-5 at 17-19). Plaintiffs also note that Defendant has produced no evidence that Plaintiffs “believed, pre-filing, that DMSO or its mixture with NMP would not work.” (D.I. 78, p. 3).

I do not believe *Tanabe* stands for the broad proposition Defendant advances. At issue in *Tanabe* was a claim directed to a method of preparing a benzothiazepine derivative. *Tanabe*, 109 F.3d at 728. The *Tanabe* court held that the International Trade Commission did not err when it concluded that the accused product’s use of the solvent butanone was not equivalent to the patentee’s recitation of the use of the solvent acetone in a method claim reciting five specific base-solvent combinations. *Id.* at 729, 734. The patentee’s recitation of the compound acetone, instead of ketones as a class of compounds, was only part of the basis for the court’s holding that butanone (also a ketone) was not equivalent. *See id.* at 732-33. The court also relied on the patentee’s representations to foreign patent offices and to the USPTO “that its specific base-solvent combinations distinguish its process from the prior art,” and the inventors’ experiments that suggested substituting butanone for acetone would not work. *Id.* at 733. During prosecution in the United States and abroad, the patentee asserted the high yields of the claimed process (at least 87%, compared to 65-70% yields for the reference process) as a reason for patentability. *Id.* at

730, 733. Additionally, experiments conducted by the patentee's expert and by the accused infringer that replaced acetone with butanone did not consistently result in yields at the same level as those of the claimed process.² *Id.* at 733. Consequently, the *Tanabe* court concluded, "a review of the prosecution history by a competitor would reinforce the suggestion in the claim language and specification that using other ketone solvents, such as butanone, is not an insubstantial change from using acetone." *Id.* at 732. Contrary to Defendant's suggestion, the patentee's recitation of a specific compound despite the existence of other well-known compounds often used for a similar purpose did not provide the sole basis for the court's holding.

I find that *Tanabe* does not compel the conclusion that Plaintiff forfeited the ability to claim equivalence of solvents other than NMP. First, the claim language at issue here is broader than the language at issue in *Tanabe*. The *Tanabe* claim is closed with respect to solvents, reciting a compound "either in the presence of potassium hydroxide in acetone or in the presence of potassium carbonate in a solvent selected from acetone, lower alkyl acetate, a mixture of acetone and water and a mixture of lower alkyl acetate and water." *Id.* at 728-29 (emphasis omitted). The claims at issue here, by contrast, are open, reciting, "A composition . . . comprising . . . from about 27.5% to about 62.5% by weight of N-methylpyrrolidone." ('011 patent, claim 1). Whereas the *Tanabe* claim language requires the selection of a solvent-base combination from those recited, the "comprising" language in the claims at issue here allows for the addition of other substances (such as additional solvents) not explicitly recited in the claims. Second, unlike the *Tanabe* patentee's statements during prosecution, the prosecution history statement that Defendant points to as a surrender of claim scope here does not explicitly distinguish the claimed formulation from

² The court noted one exception—when the accused infringer substituted butanone for acetone in an experiment using the method disclosed in Example 2 of the patent, "the reaction produced a slightly *better* yield with butanone." *Tanabe*, 109 F.3d at 733 (emphasis in original). The court discounted this exception, however, because the accused infringer "was unable to duplicate Example 2 using butanone in larger-scale pilot plant tests on two occasions." *Id.*

the prior art on the basis of the use of the particular solvent(s) claimed. (*Compare Tanabe*, 109 F.3d at 730 (“Applicants’ invention is the condensation of the acylated form . . . in the presence of potassium hydroxide in acetone or potassium carbonate in acetone, lower alkyl acetate, water-acetone, or water-lower alkyl acetate”) *with* D.I. 61-5 at 16-20 (“28 formulations were tested by Dr. Sirinyan and only the 4 compositions which are within the scope of claim 1 were successful . . . ”)). The prosecution history here merely distinguishes NMP from six other solvents that were tested and found not to work. (D.I. 61-5 at 13, 19-20). Third, unlike the record in *Tanabe*, the record here does not reflect that DMSO, the asserted equivalent, (or any solvent in the same class as DMSO) was shown to be unsuccessful in experiments. (See D.I. 59, pp. 6-8; D.I. 78, pp. 2-3). Therefore, I do not think *Tanabe* provides a basis to conclude that the patentees’ specific recitation of NMP in these claims supports concluding that Plaintiffs have forfeited their ability to argue infringement under the doctrine of equivalents.

Second, Defendant argues that claim differentiation counsels against allowing the NMP limitation of claim 1 to cover equivalent solvents. (D.I. 59, p. 5). Essentially, Defendant argues that since dependent claim 2 recites “[t]he composition of claim 1, further comprising from about 2.5% to 10% by weight of at least one cosolvent,” claim differentiation precludes claim 1 from including a cosolvent. (*Id.*). According to Defendant, if claim 1 may include a cosolvent, “then the use of the term ‘cosolvent’ in claim 2 is meaningless.”

I do not find Defendant’s claim differentiation argument convincing. It improperly ignores the specific weight limitations of the cosolvent of claim 2, and reads the “comprising” language out of claim 1. Claim 1 is a “comprising” claim. It permits, but does not require, a cosolvent. Claim 2 contains the additional limitation that a cosolvent in a specified amount must be present. If Claim 1 precluded a cosolvent, then claim 2 would be an improper dependent claim, as all of

the limitations of an independent claim must be present in any corresponding dependent claim. *See* 35 U.S.C. § 112(d).

Third, Defendant contends that by claiming unexpected results to overcome prior art during prosecution, Plaintiff forfeited the ability to assert the doctrine of equivalents of a solvent other than NMP. (*Id.* p. 6). The unexpected results underlying this argument originate in a declaration from one of the inventors (“the Sirinyan Declaration”) filed with the USPTO. (*Id.*; *see also* D.I. 61-5 at 16-20). The Sirinyan Declaration is limited, however, to the seven different solvents tested in Dr. Sirinyan’s solubility study, and the declaration draws no conclusions beyond the scope of those seven solvents. (*See* D.I. 61-5 at 16-20). Defendant also contends that the patentees argued to the examiner during prosecution that, “*only* the 4 compositions which are within the scope of claim 1 [i.e., use NMP] *were successful* in solubilizing both imidacloprid and permethrin.” (D.I. 59, p. 7 (citing D.I. 61-5 at 11-13) (brackets in original))). Defendant’s argument suggests that the patentees were distinguishing compositions that use NMP from all prior art and other solvent alternatives. The statement must be read in full context, however. It reads:

In view of the fact that a *prima facie* case of obviousness is not present in the first place for at least the reasons advanced *supra*, coupled with the fact that 28 formulations were tested by Dr. Sirinyan and only the 4 compositions which are within the scope of claim 1 were successful in solubilizing both imidacloprid and permethrin, the instant combination of Sirinyan, Dorn, and Gladney fails to render the instant claims obvious.

(*Id.*). The patentees discuss the four compositions using NMP in the context of the seven different solvents (for a total of 28 compositions) tested in the study reported in the Sirinyan Declaration. The patentees do not claim to have evaluated the four NMP-comprising compositions against all of the solvents in the prior art. Nor do the patentees claim that NMP-comprising compositions demonstrated unexpected results over any compositions other than those tested by Sirinyan and reported in the Sirinyan Declaration. Therefore, I conclude that the patentees’ unexpected results

argument to the PTO does not amount to a disclaimer of all solvents other than NMP, and does not preclude Plaintiffs from arguing infringement of compositions using solvents other than NMP under the doctrine of equivalents.

Having rejected each of Defendant's arguments, I conclude that Defendant has failed to establish its entitlement to judgment as a matter of law. I will therefore deny Defendant's motion for summary judgment. Plaintiffs may argue infringement under the doctrine of equivalents.

B. Preliminary Injunction

1. Likelihood of Success

Defendant contends that Plaintiffs' doctrine of equivalents theory is not likely to succeed on the merits. (D.I. 59, p. 8). Plaintiffs counter that they are likely to prevail on the merits, because they are not precluded from arguing infringement under the doctrine of equivalents, and because both the function-way-result test and the insubstantial differences test will yield findings that Defendant infringes. (D.I. 78, pp. 1, 9-12).

A product that does not literally infringe a patent claim may still infringe under the doctrine of equivalents if the differences between an individual limitation of the claimed invention and an element of the accused product are insubstantial. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39-40 (1997). "Insofar as the question under the doctrine of equivalents is whether an accused element is equivalent to a claimed element, the proper time for evaluating equivalency—and thus knowledge of interchangeability between elements—is at the time of infringement, not at the time the patent was issued." *Id.* at 37. The doctrine of equivalents is "applied to individual elements of the claim, not to the invention as a whole." *Id.* at 29. Under the doctrine of equivalents, "the essential inquiry [is whether] the accused product or process contain[s] elements identical or equivalent to each claimed element of the patented invention[.]

Different linguistic frameworks may be more suitable to different cases, depending on their particular facts.” *Id.* at 40. The patent owner has the burden of proving infringement by a preponderance of the evidence. *See SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988).

a. Function-Way-Result

A product may infringe under the doctrine of equivalents if it “‘performs substantially the same function in substantially the same way to obtain substantially the same result’ as the patented invention.” *Abraxis Biosci., Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370, 1379 (Fed. Cir. 2006) (quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950)). Plaintiffs concede that a proper doctrine of equivalents analysis would compare the NMP claimed in the ’011 patent with the NMP and DMSO mixture present in the accused products. (D.I. 115 at 8:15-18; *see also* D.I. 59, p. 11 (Defendant taking the same position)).

Plaintiffs’ opening brief argued that both the claimed NMP and Defendant’s NMP/DMSO mixture “function” as solvents. (D.I. 7, p. 13). They function in the same “way,” Plaintiffs wrote, because “NMP and DMSO are both in the category of polar aprotic solvents.” (*Id.*). Plaintiffs’ opening brief further maintained that the claimed NMP and Defendant’s NMP/DMSO mixture achieve the same “result,” because Plaintiffs’ product and Defendant’s products claim to have similar efficacy against fleas and ticks. (*Id.* pp. 14-15).

Defendant disputes Plaintiffs’ assertion that the claimed NMP and Defendant’s NMP/DMSO mixture function in the same way. (D.I. 59, pp. 9-10). According to Defendant, similarities in some chemical properties of NMP and DMSO are insufficient to support the equivalence of NMP and an NMP/DMSO mixture because such properties do not establish that NMP will behave the same way as an NMP/DMSO mixture. (*Id.*). Though NMP and DMSO

have, for example, similar Hansen solubility values and other chemical properties, Defendant notes that Plaintiffs' own studies demonstrated different effects of NMP and DMSO on collars soaked in each solvent. (*Id.*). Defendant offers this as proof that similarities in compounds' chemical properties are not necessarily predictive of how those compounds will behave in solution. (*Id.*). Plaintiffs' expert's assertion that properties of NMP and DMSO could predict the behavior of (1) either solvent in solution or (2) a mixture of the two solvents is unwarranted. (*Id.*). The assertion thus does not provide competent evidence that NMP and Defendant's NMP/DMSO mixture will behave in the same way in the context of the products at issue. (*Id.*). Therefore, Plaintiffs' arguments do not support a conclusion that NMP and Defendant's NMP/DMSO mixture act in the same way. (*Id.*).

As support for the "result" arguments they briefed, Plaintiffs rely on a comparison of the product label claims for K9 Advantix®II and the accused product's labeling. (D.I. 7, p. 15). The product labeling cited by Plaintiffs, however, focuses on the products as a whole rather than establishing equivalent "results" of the element at issue. (*See id.*; D.I. 11, ¶ 67). Plaintiffs further contend that Defendant's reliance on Plaintiffs' safety and efficacy data establishes that the NMP/DMSO mixture achieves the same "result" as NMP alone. (D.I. 7, p. 14).

Defendant counters that its NMP/DMSO mixture yields different results than NMP alone. (D.I. 59, pp. 10-11). As support, Defendant offers results from a clinical study of the accused products. (*Id.*) According to Defendant's expert, the study results would likely lead to a European label claim of 4 weeks' efficacy against Dermacentor ticks. (D.I. 61-1, ¶¶ 124-27). Defendant maintains this is a significant improvement over the K9 Advantix®II product's three-week European label efficacy claim against Dermacentor ticks. (D.I. 59, pp. 10-11). There may be a difference in efficacy against Dermacentor ticks between K9 Advantix®II and the accused

products. Any such difference does not provide competent evidence for the doctrine of equivalents analysis, however, because it is derived from a comparison of the invention as a whole to the accused product, rather than focusing on the element at issue. *See Warner-Jenkinson Co.*, 520 U.S. at 29.

I find Plaintiffs' briefed function-way-result analysis deficient. First, though Plaintiffs contend that the claimed NMP and Defendant's NMP/DMSO mixture function in the same "way," Plaintiffs offer no supporting evidence that compares NMP and any NMP/DMSO mixture. (*See* D.I. 7, pp. 13-14). Despite agreeing that the proper function-way-result analysis compares NMP to Defendant's NMP/DMSO mixture, Plaintiffs' "way" analysis compares NMP to DMSO. (*Id.*; *see also* D.I. 115 at 8:15-18). Plaintiffs' evidence thus fails to address the proper inquiry. Second, I find that neither Plaintiffs' comparison of product label claims nor Defendant's reliance on Plaintiffs' EPA data provides an adequate basis to conclude that NMP and Defendant's NMP/DMSO mixture achieve Plaintiffs' proffered "result." The products' label claims and the data submitted to the EPA fail to address the proper inquiry, because they concern the safety and efficacy of the products as a whole, rather than focusing on the limitation at issue. *See Warner-Jenkinson Co.*, 520 U.S. at 29; *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1298 (Fed. Cir. 2009) (en banc) (rejecting argument that claiming bioequivalence to FDA was an admission of infringement by equivalents because "[b]ioequivalency is a regulatory and medical concern aimed at establishing that two compounds are effectively the same for pharmaceutical purposes" whereas "equivalency for purposes of patent infringement requires an element-by-element comparison of the patent claim and the accused product.")). Therefore, I conclude that the arguments Plaintiffs briefed fail to establish likelihood of success under the function-way-result test.

During oral argument, Plaintiffs asserted that Defendant's NMP/DMSO mixture is equivalent to Plaintiffs' claimed NMP because Defendant's "mixture does exactly what NMP is contemplated" to do—the "result" is "the stable homogeneous mixture of the active ingredients in the correct concentration . . . for the product to be applicable as the claimed spot-on product." (*Id.* at 8:22-23, 9:1-4). Plaintiffs also argued that the function "is to form this kind of stable homogeneous product," and "[t]he way it does that is [] that it acts as a solvent." (D.I. 115 at 9:6-8).

Though Plaintiffs' oral argument function-way-result analysis properly compares NMP to Defendant's NMP/DMSO mixture, I do not find Plaintiffs' analysis convincing. The function and result that Plaintiffs identify are essentially the same—Plaintiffs' "function" is to "form this kind of stable homogeneous product," and its "result" is "the stable homogeneous mixture of the active ingredients in the correct concentration." (D.I. 115 at 9:1-4, 9:7-8). The only difference between the two is that Plaintiffs' "result" specifies that the active ingredients must be in the correct concentrations. (*Id.* at 9:1-4, 9:7-8). The "function" recites product stability and homogeneity, thereby requiring that the active ingredients be soluble in the solvent (i.e., the active ingredients cannot precipitate or form crystals in the solution). Achieving the result becomes a question of the amount of solvent added to the active ingredients, as the "function" accounts for the relevant properties of the solvent. Additionally, Plaintiffs' recited "way" is acting as a solvent. (*Id.* at 9:6). By definition, a solvent dissolves a solute to form a homogeneous solution. Plaintiffs' recited function already requires formation of a homogeneous solution. Therefore, Plaintiffs' recited "way" adds nothing to its recited "function."

I further find Plaintiffs' oral argument function-way-result analysis overbroad, because it seems to capture as an equivalent any solvent that would work to dissolve the active ingredients,

regardless of the solvent's similarity to NMP. Finally, since the function-way-result analysis in Plaintiffs' briefing did not provide evidence comparing NMP to Defendant's NMP/DMSO mixture, Plaintiffs' written analysis does not adequately support Plaintiffs' oral argument analysis. Accordingly, I conclude that Plaintiffs have failed to establish likelihood of success under the function-way-result test.

b. Insubstantial Differences

Given the deficiencies in Plaintiffs' function-way-result analysis, the facts here may be better suited to a doctrine of equivalents analysis under the "insubstantial differences" test. *See Mylan Institutional, LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 869 (Fed. Cir. 2017) ("[T]he substantial differences test may be more suitable than FWR for determining equivalence in the chemical arts.").

Plaintiffs appear to argue that since NMP and DMSO demonstrate similarities in chemical properties relevant to their use as solvents in the claimed formulation, NMP is substantially similar to Defendant's NMP/DMSO mixture. (*See* D.I. 7, p. 14). Plaintiffs' acknowledgement that a comparison of NMP and DMSO is not the proper analysis undermines this argument. (D.I. 78, p. 10). Additionally, Plaintiffs rely on an admission to the PTO by the accused products' inventor that at least some undisclosed amount of NMP or N-ethylpyrrolidone is necessary to the accused product. (*Id.* p. 11). Plaintiffs suggest that this supports an inference that Defendant copied Plaintiffs' invention, merely adding DMSO to make up for the NMP Defendant removed. (*Id.* pp. 11-12). I find this argument unconvincing. Taken to its logical conclusion, Plaintiffs' argument would support an inference of copying even for a product with just a minimal amount of NMP, say, 1%. That some NMP is required does not compel the conclusion that Defendant copied

Plaintiffs' product. I agree with Defendant that its experiments with various solvents are more supportive of inferring efforts to design around, rather than mere copying. (*See* D.I. 59, p. 11).

Defendant maintains that the many months of "extensive experimentation" required to develop the NMP/DMSO mixture supports a finding that the NMP/DMSO mixture "is not readily interchangeable" with NMP in the claimed formulation. (*Id.*). The experiments to develop Defendant's accused products began in 2013 and continued until Defendant reached the final formulation in April 2015. (D.I. 60, ¶¶ 8, 10). Therefore, Defendant maintains that the NMP/DMSO mixture is substantially different from NMP in the claimed formulation. (*Id.*). The experiments support an inference that NMP and an NMP/DMSO mixture were not readily interchangeable at the time of invention. Since the experiments are relatively close in time to the claimed infringement, they also provide some evidence that NMP and an NMP/DMSO mixture were not considered readily interchangeable at the time of infringement, when equivalence is properly assessed. *See Warner-Jenkinson Co.*, 520 U.S. at 37.

Plaintiffs dispute Defendant's characterization of the amount of time spent developing the accused product. (D.I. 78, p. 11). As support, Plaintiffs offer the accused product's inventor's deposition testimony that he spent twenty or thirty minutes running initial tests of three or four solvents before turning to a third-party company to test various solvents in formulations for the accused product. (*Id.* (citing D.I. 79 at 7)). Plaintiffs contend that this undermines Defendant's argument that NMP and the NMP/DMSO mixture are substantially different. (*Id.*).

I do not find that the cited deposition testimony clearly establishes DMSO as the first solvent to try. Even if it did, however, it alone would not establish that there are no substantial differences between NMP and the NMP/DMSO mixture. Though Plaintiffs acknowledge that the proper comparison is between NMP and the NMP/DMSO mixture, Plaintiffs have offered no

evidence that directly compares the two. I find Plaintiffs' evidence comparing NMP in isolation and DMSO in isolation, and its evidence regarding DMSO as a substitute for NMP, insufficient to support an inference that there is no substantial difference between NMP and the NMP/DMSO mixture in Defendant's products.

c. Validity

A party may successfully oppose the imposition of a preliminary injunction by "put[ting] forth a substantial question of invalidity to show that the claims at issue are vulnerable." *Erico Intern. Corp. v. Vutec Corp.*, 516 F.3d 1350, 1356 (Fed. Cir. 2008). "[A] showing of a substantial question of invalidity requires less proof than the clear and convincing standard to show actual invalidity." *Id.*

Defendant argues that Plaintiffs are not likely to succeed on the merits because there is a substantial question of whether the '011 patent is valid. (D.I. 59, p. 11). According to Defendant, the Sumitomo patent, the Dorn patent, the Arther reference, and the Brouwer commercial product render the '011 patent obvious because they disclose all of the elements of the claimed invention, and a person of ordinary skill would have a motivation to combine them with a reasonable expectation that the combination would work. (*Id.* p. 12). These references disclose spot-on formulations for controlling parasites on animals, and Defendant maintains that "the desire to create a combination product to compete with Frontline provided every motivation to combine" them. (*Id.* (citing D.I. 61-1, ¶¶ 146-48)). Defendant argues that the Brouwer commercial spot-on product, advertised in a printed and publicly available Spanish technical journal, provided a reasonable expectation of success because it disclosed an antiparasitic spot-on medication for dogs that contains imidacloprid and permethrin. (*Id.* pp. 12-13; D.I. 61-12 at 71-80). Since Sumitomo and Dorn teach the use of "a short list of liquid carrier[]" solvents, including NMP, in spot-on

formulations, Defendant submits that NMP would have been an obvious solvent to try in a permethrin and imidacloprid formulation. (D.I. 59, p. 13).

Plaintiffs respond that Defendant's analysis is tainted by hindsight bias. (D.I. 78, p. 12). As a threshold matter, Plaintiffs note that the patentees disqualified the Arther reference from being prior art during prosecution of the '011 patent by demonstrating invention prior to Arther's filing date. (*Id.* p. 12 n.11; D.I. 61-3 at 32-33, 35-38). Plaintiffs criticize Brouwer as "a compilation of documents" that fails to disclose whether the formulation is a solution, the solvent used, or an amount of permethrin within the claims of the '011 patent. (D.I. 78, p. 13). Plaintiffs further characterize the Sumitomo and Dorn references as "too diffuse to be relevant," and note that none of the examples of formulations in these references mention permethrin or NMP. (*Id.*; *see* D.I. 61-4 at 28-30; D.I. 61-11 at 53).

Sumitomo does not explicitly identify imidacloprid, but it is "one of the thousands of possibilities within depicted Formula 2," which allows variation in four different chemical groups of the claimed compound. (D.I. 78, p. 12; D.I. 61-11 at 50 (representing variable groups in Formula 2 with "A," "Z," "X," and "Y," and using "n" to indicate permissible variation in the number of methylene groups)). Though Sumitomo identifies NMP and permethrin, it recites NMP as one of seven possible and optional solvents for the claimed formulation, and recites permethrin as one of 54 optional active ingredients (and several classes of compounds) that may be present in the claimed formulation. (D.I. 78, pp. 12-13; D.I. 61-11 at 53).

Similarly, Dorn discloses imidacloprid as an example of one of about twenty compounds that can be used. (D.I. 61-4 at 19). The scope of Dorn's formulations is not limited to solutions—it includes "emulsions and suspensions" and "solid preparations," which are disclosed as "suitable preparations" for "dermal administration" of the invention. (*Id.* at 21). Dorn discloses NMP as

one potential solvent in a list that includes roughly 25 other solvent genuses and species. (*Id.*). Permethrin is disclosed as one of seven options for “formula I” that may be included in the formulation. (*Id.* at 26).

Finally, Plaintiffs cite Defendant’s expert’s statements that “there can be no predictability of solvent behavior in a formulation especially when there are multiple active ingredients, excipients and antioxidants in the formulation” and “there can be no expectation of success that substituting . . . closely related solvents for each other in a complex formulation would work in the same way to achieve the same result as the original solvent.” (D.I. 78, p. 15 (citing D.I. 61-1, ¶ 112)).

I agree with Plaintiffs. Defendant’s argument that Sumitomo and Dorn teach “a short list of carriers” to test ignores the fact that none of Defendant’s references specifically disclose combining permethrin and imidacloprid. Rather, these references recite imidacloprid, permethrin, and NMP within larger lists of suitable compounds for use in spot-on formulations. Even assuming that a person of ordinary skill would start with imidacloprid, Defendant’s references provide for hundreds if not thousands of possible formulations. Defendant has not offered any reason that a person of ordinary skill seeking to formulate an alternative to Frontline’s fipronil product would opt to combine NMP, permethrin, and imidacloprid from among these many possible combinations. Finally, even assuming that a person of ordinary skill had a motivation to combine Defendant’s proffered references, Defendant’s own expert stated that there would be no expectation of success in a formulation with multiple active ingredients. (D.I. 61-1, ¶ 112). Therefore, I conclude that Defendant has failed to raise a substantial question regarding the validity of the ’011 patent.

2. Irreparable Harm

“It is well established that [] the party seeking injunctive relief [] ‘must make a clear showing that it is at risk of irreparable harm, which entails showing a likelihood of substantial and immediate irreparable injury.’” *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012) (citations omitted). “[T]o satisfy the irreparable harm factor in a patent infringement suit, a patentee must establish both of the following requirements: 1) that absent an injunction, it will suffer irreparable harm, and 2) that a sufficiently strong causal nexus relates the alleged harm to the alleged infringement.” *Id.* “To show irreparable harm, it is necessary to show that the infringement caused harm in the first place. . . . Thus, a likelihood of irreparable harm cannot be shown if sales would be lost regardless of the infringing conduct.” *Apple Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012). Moreover, deciding whether a plaintiff would suffer irreparable harm absent an injunction involves an inquiry into whether money damages would adequately make the plaintiff whole. *See Celsis in Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) (“[T]he irreparable harm inquiry seeks to measure harms that no damages payment, however great, could address.”).

Plaintiffs argue that “the targeted marketing of [Defendant’s] generics is uniquely accelerating a decline in K9 Advantix®II sales and damaging [Plaintiff] in a manner that a post-trial award would not fully compensate.” (D.I. 78, p. 15; *see also* D.I. 7, p. 16; D.I. 115 at 18:17-19:1). Since the accused product is “basically [K9 Advantix®II] at a lower price,” Plaintiff contends Defendant’s products “disproportionately affect the sale of [Plaintiffs’] products versus other spot-on products.” (D.I. 115 at 18:17-25). According to Plaintiffs, the effects will be “particularly acute in the pet specialty channel, which accounts for most of [Plaintiffs’] revenue and profits from K9 Advantix®II.” (D.I. 7, p. 16). Though they do not sell products directly into

the multi-outlet channel, Plaintiffs also submit that they will suffer irreparable harm in the multi-outlet channel, “[b]ecause some K9 Advantix®II sold by [Plaintiffs] is diverted to [that] channel.” (*Id.* p. 17). In the multi-outlet channel, K9 Advantix®II sells “at prices just below those in the pet specialty channel,” and Plaintiffs argue that competition from Defendant’s generic product in the multi-outlet channel will drive K9 Advantix®II prices even lower. (*Id.*). Citing as precedent the response of Frontline’s branded spot-on product to generic market entry, Plaintiffs further assert that, “[i]nvariably, customers will move to the [multi-outlet] channel stores from the pet specialty channel to purchase essentially the same product as K9 Advantix®II at an even lower price.”³ (*Id.*). Customers will become accustomed to the lower price, and even if the accused product is removed from the market after the litigation, customers “likely will not switch back to K9 Advantix®II, and certainly not at its pre-generic pricing.” (*Id.*). Instead, Plaintiffs assert customers will “more likely switch to another low-cost spot-on product, such as the generics to the Frontline® product.” (*Id.*).

³ Plaintiffs’ preliminary injunction reply brief (D.I. 78) was accompanied by a declaration from Dr. Alan White (D.I. 81). Defendant has moved to strike Dr. White’s declaration, arguing that Plaintiffs’ reply brief relies on the declaration to present “a new theory of irreparable harm” not presented in Plaintiffs’ opening brief. (D.I. 96). According to Defendant, Dr. White’s declaration advances an “accelerated decline model” of irreparable harm based on targeted marketing to replace Plaintiffs’ original “permanent displacement model” of irreparable harm. (D.I. 105, p. 3). Allowing Plaintiffs to present this new theory is prejudicial, Defendant argues, because Dr. White’s opinions rely on “late-produced documents and exhibits,” and his testimony “has not been vetted in discovery.” (D.I. 101, pp. 7-8). Whereas Plaintiffs relied in their opening brief solely on an analogy to the Frontline Plus experience with generic entry, Plaintiffs now seek to rely on “late-produced survey data on customer preferences” and three exhibits created by Dr. White. (D.I. 97, pp. 6-7). Plaintiffs respond that Dr. White’s opinions do not present a new theory, and instead amount to “a demonstration, with evidence of sales history not originally available, of a concept that was expressed in the original [expert] declarations” submitted with their opening brief. (D.I. 101, p. 6).

I do not view Plaintiffs’ accelerated decline model as a new theory. Plaintiffs’ opening brief argues that Defendant “specifically targets K9 Advantix®II with its advertising in pet specialty channel stores displaying K9 Advantix®II packaging side-by-side with [Defendant’s product] packaging and a banner stating that [Defendant’s product] has ‘the same active ingredients as’” Plaintiffs’ product. (D.I. 7, p. 16 (emphasis added)). Regardless, my conclusions do not depend on which evidence Plaintiffs rely on to support their irreparable harm theory. Whether Plaintiffs rely on sales data or Frontline Plus’s prior experience with generic entry to support lost sales and market share, Plaintiffs have failed to adequately address Defendant’s arguments against irreparable harm. *See infra* 24 n.4. Further, many of the disputed portions of Plaintiffs’ reply brief rely on Dr. White’s declaration in parallel with Mr. Van Brunt’s second declaration, to which Defendant does not object. (*See* D.I. 78, pp. 16-17; D.I. 96). Mr. Van Brunt’s second declaration may thus provide adequate support for many of Plaintiffs’ reply arguments. Additionally, Defendant raised no objections to Plaintiffs’ presentation of their accelerated decline model or Dr. White’s testimony during oral argument. (*See* D.I. 115, 49-52). Accordingly, Defendant’s motion to strike Dr. White’s declaration is dismissed as moot.

Therefore, if the accused product remains on the market during the litigation, the spot-on product market share of K9 Advantix®II will irreversibly decrease, and Plaintiffs will be forced to sell K9 Advantix®II at a lower price. (*Id.* p. 16).

Defendant counters that Plaintiffs' assertion of irreparable harm rests on flawed litigation-based models that fail "to account for any variable impacting sales other than the generic entrant." (D.I. 59, p. 14). As support for the inadequacy of Plaintiffs' models, Defendant offers several of Plaintiffs' business documents, which forecast and attribute lost K9 Advantix®II sales to factors other than generic market entry. (*Id.* pp. 16-17). Such factors include Plaintiffs' head-to-head marketing of the Seresto collar with K9 Advantix®II, customer migration from pet specialty to online vendors, branded competition targeting K9 Advantix®II, and customers following vet recommendations for orally administered products. (*Id.*). Citing Plaintiffs' 2017 K9 Advantix®II Brand Management Plan, Defendant contends that Plaintiffs recognized that their K9 Advantix®II product was declining because it "is an aging product lacking innovation." (D.I. 115 at 51:2-20; *see also* D.I. 8-1 at 329 (reciting "aging product" and "lack of innovation" among the weaknesses of the K9 Advantix®II product)). To further counter Plaintiffs' assertion of irreparable harm, Defendant offers Plaintiffs' internal documents from February 2017 and deposition testimony of Plaintiffs' expert from September 2017 indicating that Plaintiffs planned to increase the price of K9 Advantix®II by 3% for 2018. (D.I. 59, p. 18 (citing D.I. 63-9 at 80; D.I. 63-5 at 34)). Finally, Defendant asserts that Plaintiffs' delay in filing this motion suggests that Plaintiffs have not suffered irreparable harm. (*Id.* pp. 18-19 (noting that Plaintiffs waited until June 2017 to file their motion, despite receiving a description of the accused formulation in April 2015); D.I. 115 at 47:16-22 (noting that Plaintiff received test results "as early as March 7, 2017, and yet they still wait[ed] 13 weeks to file their Preliminary Injunction Motion"))).

I find that Plaintiffs have failed to provide sufficient evidence of irreparable harm. Though Plaintiffs maintain that Defendant “overstates in effect” the factors other than generic product entry, Plaintiffs’ reply brief addresses only two of the roughly fifteen other factors raised by Defendant.⁴ (D.I. 78, pp. 15-16 (discussing Plaintiffs’ Seresto collar and Plaintiffs’ PetSmart promotional program)). The multi-competitor nature of the spot-on market, the general decline of spot-on products, and customer migration away from the pet specialty channel suggest that factors other than Defendant’s product may be responsible for the decline in K9 Advantix®II sales. Additionally, Plaintiffs’ lack of evidence of any consideration of a price drop for K9 Advantix®II seems inconsistent with their assertions of irreparable harm. Therefore, I conclude that Plaintiffs have failed to establish irreparable harm.

Having concluded that Plaintiffs have demonstrated neither a likelihood of success on the merits nor irreparable harm, I need not address the other two preliminary injunction factors. *Jack Guttman*, 302 F.3d at 1356. I will deny Plaintiffs’ motion for preliminary injunction.

IV. CONCLUSION

For the reasons stated above, Plaintiffs’ motion for preliminary injunction and Defendant’s motion for summary judgment are **DENIED**.

⁴ Plaintiffs’ reply brief states that “Dr. White’s Declaration, at ¶¶ 23 and 48-57, addresses [Defendant’s] other alleged sales-stealing factors.” (D.I. 78, p. 16). I find that incorporating multiple pages of an expert declaration by reference is not an adequate substitute for briefing responses to arguments raised by the opposing party. Therefore, Plaintiffs have failed to adequately address factors aside from Plaintiffs’ Seresto collar and the PetSmart promotional program.